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28075	7590	04/05/2006	EXAMINER	
CROMPTON, SEAGER & TUFTE, LLC			SMITH, PAUL B	
1221 NICOLLET AVENUE			ART UNIT	
SUITE 800			PAPER NUMBER	
MINNEAPOLIS, MN 55403-2420			3763	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/749,499

Applicant(s)

GUNDERSON, RICHARD C.

Examiner

Paul B. Smith

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3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/04, 4/04, & 6/05
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements (IDS) submitted on 3/26/2004, 4/15/2004, and 6/13/2005 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner considers the references cited therein.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

3. In claim 20, the specification makes no mention of "longitudinal deflections". As a result it is unclear what the applicant is intending to claim.

4. In claim 24, the specification fails to teach an outer layer comprising multiple segments of polymeric material. The specification does provide for an outer layer comprising multiple polymeric materials, but does not mention multiple segments for the purpose of property variations.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 20 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 20 recites the limitation "Longitudinal deflection" in line 4-5. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 24 recites the limitation "multiple segments" in line 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

10. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

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Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claims 1-2, 4-5, 7-9, 12-15 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by McBroom *et al.* ('108).

12. As to Claim 1-2, 4, 7, 21 and 23, McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer layer extends from the outer surface into the opening of the marker band. (See Figure 1, 3, 5 and Column 5 Lines 8-10)

13.

14. As to Claim 5, McBroom *et al.* discloses a marker band comprising horizontal perforations encircling the marker band. (See Figure 7)

15.

16. As to Claim 8-9, McBroom *et al.* discloses a marker band comprising a top surface (508), a bottom surface (510) and vertical perforations (512) extended from the top surface to the bottom surface. (See Figure 6)

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17. As to Claim 12-15, McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer surface of the marker can be coated with adhesive to secure it to the outer layer. The core of the tubular member comprises either a catheter or guidewire. (See Figure 1, 3, 5; Column 4 Lines 65-66 and Column 3 Lines 30-35)

18. Thus, McBroom *et al.* appears to reasonably teach every element of claims 1-2, 4-5, 7-9, 12-15 and 23.

19. Claims 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee *et al.* ('934).

20. As to claims 16-18, Lee *et al.* discloses a radiopaque marker band comprising a generally cylindrical body (40), a first slot (41a) and a second slot (41b) in the proximal and distal end regions respectively. The first and second slots have axially aligned opposing slots within the cylindrical body. (See Figure 4a)

21. Thus, Lee *et al.* appears to reasonably teach all the elements of claims 16-18.

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

24. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over McBroom *et al.* ('108).

25. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer layer extends from the outer surface into the opening of the marker band. (See Figure 1, 3, 5 and Column 5 Lines 8-10)

26. McBroom *et al.* further discloses a marker band comprising horizontal perforations encircling the marker band. (See Figure 7)

27. McBroom *et al.* discloses a marker band comprising a top surface (508), a bottom surface (510) and vertical perforations (512) extended from the top surface to the bottom surface. (See Figure 6)

28. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer surface of the marker can be coated with adhesive to secure it to the outer layer. The core of the tubular member comprises either a catheter or guidewire. (See Figure 1, 3, 5; Column 4 Lines 65-66 and Column 3 Lines 30-35)

29. McBroom *et al.* fails to disclose a radiopaque band marker that comprise a plurality openings that are generally defined as ovals.

30. It would have been obvious to one skilled in the art at the time of the invention to recognize that the openings could comprise an oval shape to provide better visualization. Since the applicant does not disclose a specific reason for the shape of the openings, and does not disclose any criticality to, or unexpected results from this configuration, such a configuration is considered obvious to one skilled in the art, wishing for certain results.

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31. Claims 6, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over McBroom *et al.* ('108).

32. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer layer extends from the outer surface into the opening of the marker band. (See Figure 1, 3, 5 and Column 5 Lines 8-10)

33. McBroom *et al.* further discloses a marker band comprising horizontal perforations encircling the marker band. (See Figure 7)

34. McBroom *et al.* discloses a marker band comprising a top surface (508), a bottom surface (510) and vertical perforations (512) extended from the top surface to the bottom surface. (See Figure 6)

35. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer surface of the marker can be coated with adhesive to secure it to the outer layer. The core of the tubular member comprises either a catheter or guidewire. (See Figure 1, 3, 5; Column 4 Lines 65-66 and Column 3 Lines 30-35)

36. McBroom *et al.* fails to disclose a radiopaque band marker that comprise a plurality openings that are offset or staggered or both.

37. It would have been obvious to one skilled in the art at the time of the invention to recognize that the openings could comprise a staggered or offset configuration to allow for irregular catheter geometries or provide better three-dimensional visualization of the band marker. Since the applicant does not disclose a specific reason for the staggered or offset openings, and does not disclose any criticality to, or unexpected results from this configuration, such a configuration is considered obvious to one skilled in the art, wishing for certain results.

38. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over McBroom *et al.* ('108) in view of MacDonald ('369).

39. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer layer extends from the outer surface into the opening of the marker band. (See Figure 1, 3, 5 and Column 5 Lines 8-10)

40. McBroom *et al.* further discloses a marker band comprising horizontal perforations encircling the marker band. (See Figure 7)

41. McBroom *et al.* discloses a marker band comprising a top surface (508), a bottom surface (510) and vertical perforations (512) extended from the top surface to the bottom surface. (See Figure 6)

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42. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer surface of the marker can be coated with adhesive to secure it to the outer layer. The core of the tubular member comprises either a catheter or guidewire. (See Figure 1, 3, 5; Column 4 Lines 65-66 and Column 3 Lines 30-35)

43. McBroom *et al.* fails to teach an outer surface that is defined by a fluorocarbon polymer.

44. MacDonald teaches an inner tubular sheath comprising a fluorocarbon or other lubricous polymer. (See Column 6 Line 26-40)

45. It would have been obvious to one skilled in the art to combine the disclosure of McBroom *et al.* with the teachings of MacDonald to provide a tubular member that includes an outer surface defined by a fluorocarbon.

46. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over McBroom *et al.* ('108) in view of Waldhauser *et al.* ('956).

47. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band

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comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer layer extends from the outer surface into the opening of the marker band. (See Figure 1, 3, 5 and Column 5 Lines 8-10)

48. McBroom *et al.* further discloses a marker band comprising horizontal perforations encircling the marker band. (See Figure 7)

49. McBroom *et al.* discloses a marker band comprising a top surface (508), a bottom surface (510) and vertical perforations (512) extended from the top surface to the bottom surface. (See Figure 6)

50. McBroom *et al.* discloses a medical device comprising a tubular member (120), a radiopaque marker band (160) and an outer layer (140). The radiopaque marker band comprises an inner surface (404) and an outer surface (402) with one or more openings (410) through the outer surface. The outer surface of the marker can be coated with adhesive to secure it to the outer layer. The core of the tubular member comprises either a catheter or guidewire. (See Figure 1, 3, 5; Column 4 Lines 65-66 and Column 3 Lines 30-35)

51. McBroom *et al.* fails to teach a method of manufacturing a medical device .

52. Waldhauser *et al.* discloses a method of manufacturing a medical device comprising disposing a marker band over a pull wire and disposing a heat shrink over the pull wire and marker band. The heat shrink acts as a coating that retains the marker band in place. (See Figure 11)

53. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Waldhauser *et al.* to provide a method for manufacturing the disclosed medical device of McBroom *et al.*

54. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lee *et al.* ('934).

55. As to claims 16-18, Lee *et al.* discloses a radiopaque marker band comprising a generally cylindrical body (40), a first slot (41a) and a second slot (41b) in the proximal and distal end regions respectively. The first and second slots have axially aligned opposing slots within the cylindrical body. (See Figure 4a)

56. Lee *et al.* fail to disclose slots that are staggered.

57. It would have been obvious to one skilled in the art at the time of the invention to recognize that the openings could comprise a staggered or offset configuration to allow for irregular catheter geometries or provide better three-dimensional visualization of the band marker. Since the applicant does not disclose a specific reason for the staggered or offset openings, and does not disclose any criticality to, or unexpected results from this configuration, such a configuration is considered obvious to one skilled in the art, wishing for certain results.

Conclusion


58. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul B. Smith whose telephone number is 571-272-6022. The examiner can normally be reached on 8 am - 4 pm.

59. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

60. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul B Smith
Examiner
Art Unit 3763

PBS
3/31/06


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